UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND

COMPOUNDING PHARMACY, INC. PRODUCT LIABILITY LITIGATION

THIS DOCUMENT RELATES TO:

MDL No. 13-2419-RWZ-JCB

Mattila v. New England Compounding

Pharmacy, Inc.

Case No. 1:13-cv-10430

STATEMENT OF INTEREST BY THE UNITED STATES

The United States respectfully submits this statement of interest on behalf of the U.S.

Department of Health and Human Services ("HHS") and its Centers for Medicare & Medicaid

Services ("CMS") in response to Plaintiff Milda Mattila's Motion for Equitable and/or

Declaratory Relief Regarding Outstanding Medicare Lien, ECF No. 3566 (hereinafter

"Motion").¹ The United States submits this statement under 28 U.S.C. § 517, which permits the

Attorney General to attend to the interests of the United States in any case pending in a federal court.² The Motion asks the Court to limit the government's statutory right to reimbursement for Mattila's healthcare costs from her settlement in this case. This statement provides information about a prior federal court ruling dismissing this same request and discusses jurisdictional and procedural bars to ruling on the Motion.

¹ Ms. Mattila is deceased; the movant is the personal representative of her estate.

² Title 28, Section 517 of the U.S. Code permits the Attorney General to attend to the interests of the United States in any case pending in a federal court. The United States uses that authority to make federal courts aware of government interests in cases where the United States is not a party. Filing a statement of interest or appearing under 28 U.S.C. § 517 does not constitute intervention or make the United States a party to a litigation.

As described more fully below, the United States respectfully submits that the Motion should be denied for two separate reasons. *First*, the Court lacks subject matter jurisdiction over Mattila's request. To establish jurisdiction over claims seeking relief from the government, a plaintiff must identify a statutory waiver of sovereign immunity. The Motion identifies no such waiver, and none exists. Instead, the Medicare statute specifically precludes subject matter jurisdiction over Mattila's request until she exhausts CMS's administrative review process. *See* 42 U.S.C. § 1395ii (incorporating 42 U.S.C. § 405(h)). Indeed, a sister district court already ruled against Mattila on this very basis, in a lawsuit she brought against CMS seeking the same relief requested here. *Mattila v. CMS*, No. 19-cv-10446, 2020 WL 532400, at *7–8 (E.D. Mich. Feb. 3, 2020). The Motion does not allege that Mattila has since completed, or even initiated, the administrative process. Unless and until she does so, collateral estoppel bars Mattila from relitigating the issue.

Second, the Motion asks the Court to limit the HHS's right to reimbursement from Mattila's NECC tort settlement funds. Mot. ¶ 17. But neither HHS nor HHS Secretary Xavier Becerra (in his official capacity) has been served with a pleading or a summons in this litigation. The Motion is therefore procedurally defective.

BACKGROUND

A. CMS's Right to Recover Medicare Conditional Payments

Medicare is a federal program that provides federally funded health insurance for the elderly and certain people with disabilities. CMS, an agency within HHS, administers the Medicare program. As first enacted, Medicare was generally a "primary" payer for medical services, meaning it paid beneficiary health claims first, even when such health claims were covered by other insurance. "[B]eginning in 1980, Congress enacted a series of cost cutting

amendments to the Medicare program," which "are collectively known as the Medicare as Secondary Payer ('MSP') statute." *Fanning v. United States*, 346 F.3d 386, 388 (3d Cir. 2003). The MSP statute, 42 U.S.C. § 1395y(b)(2), is designed to "lower[] overall federal Medicare disbursements by requiring Medicare beneficiaries to exhaust" other healthcare coverage "before resorting to their Medicare coverage." *United States v. R.I. Insurers' Insolvency Fund*, 80 F.3d 616, 618 (1st Cir. 1996).

The MSP statute prohibits Medicare from paying for an item or service when payment has been made, or can reasonably be expected to be made, by a primary payer (i.e., a "primary plan"), such as a group health plan or liability insurer (including a tortfeasor). See 42 U.S.C. § 1395y(b)(2)(A). In cases where Medicare is the secondary payer but primary payment is delayed or in dispute, Medicare may make conditional payments for covered items and services. See id. § 1395y(b)(2)(B)(i). Primary payers must then reimburse Medicare when their responsibility for conditional payments is established, by, for example, a settlement. See id. § 1395y(b)(2)(B)(i)—(ii). Once a primary payer's responsibility has been established, any "entity that receives payment from [the] primary plan" is required to reimburse Medicare. Id. § 1395y(b)(2)(B)(ii). Where, as here, reimbursement results from a tort settlement, CMS reduces its claim for reimbursement of conditional payments to account for attorney's fees and other costs of procuring the award. See 42 C.F.R. § 411.37.

B. The MSP Agreement and Mattila's Opt Out

In May 2015, the United States Bankruptcy Court for the District of Massachusetts approved settlement agreements with New England Compounding Pharmacy Inc., d/b/a New England Compounding Center ("NECC") and associated entities and established the NECC Tort Trust. *See* Notice of Entry of Confirmation Order, Ex. A ¶ 26, 29, ECF No. 1890-1. A little

more than a year later, the United States, on behalf of HHS (and its agency CMS), and the NECC Tort Trustee executed a global MSP settlement agreement that ensured that the Trustee would comply with the Trustee's obligations to reimburse Medicare under the MSP statute and streamlined the process for resolving the government's MSP reimbursement rights with respect to Medicare beneficiaries who did not opt out.³ *See* Lead Counsel's Report to the Ct.

Concerning Status of Agreement Between the Tort Trustee & CMS, Ex. A, ECF No. 3068-1 (hereinafter "MSP Agreement").⁴ In the MSP Agreement, HHS agreed to accept MSP reimbursement based on negotiated percentages of Medicare-entitled claimants' NECC settlement allocations, *see* MSP Agreement § I, rather than requiring the typical, fact-intensive administrative process needed to identify and resolve reimbursement for the conditional payments made on behalf of each claimant.

Participation in the streamlined process was voluntary, and Medicare beneficiaries were given the opportunity to opt out of the agreement if they wished to resolve their MSP reimbursement obligations individually. Beneficiaries had 30 days to opt out once they were given notice by the NECC Tort Trustee of the streamlined process and their entitlement to optout. *See id.* § IV. The MSP Agreement stated that, by opting out, the claimant "agree[d] to negotiate individually with CMS . . . to resolve CMS' . . . claim(s)," and described how to begin CMS's administrative process. *Id.* § IV–IV.A. The MSP Agreement additionally stated that its negotiated percentages would not apply to opt-out claimants:

Once a Claimant submits a Timely Notice of Lien Opt-Out to the NECC Tort Trustee, the Negotiated Lien Payment Amount as reflected in Attachment B, and any other term of this Agreement, shall not apply with respect to any payments

³ The MSP Agreement also resolved CMS's MSP reimbursement rights with respect to a fund created under a class action settlement in *Adair v. Michigan Pain Specialists, PLLC*, No. 14-28156-NO (Mich. Cir. Ct., Livingston Cnty.), that is not at issue in the Motion.

⁴ The Motion refers to the MSP Agreement as the "Lien Resolution Program."

made by the Five Settlement Funds to the Opt-Out Medicare-Entitled . . . Claimant . . . and shall not bind CMS . . . in any individual negotiation or resolution of the amount owed CMS . . . by the Claimant.

Id. § IV. At the request of Lead Counsel for the Plaintiffs' Steering Committee, the Court approved the settlement by order dated August 24, 2016. *See* Order on Mot. for Approval of Agreement Between the Tort Trustee & CMS, ECF No. 3073.

By letter dated December 28, 2016, Mattila's attorney-in-fact "voluntarily and knowingly" opted-out of the MSP Agreement on her behalf, expressly acknowledging that doing so meant it became "Claimant's responsibility to resolve any claims that the [CMS] [] may have against [her] for health care cost reimbursement." *See* Exhibit A (signed opt-out notice). In accordance with the MSP statute, CMS has asserted a right to reimbursement of the Medicare conditional payments made on Mattila's behalf from the NECC settlement funds awarded to her. Mattila does not dispute that she is required to reimburse Medicare's conditional payments from her settlement funds. However, through a "prayer and request for equitable and/or declaratory relief," the Motion asks the Court to deprive the government of much of its statutory claim for reimbursement. Mot. ¶ 17.

DISCUSSION

The United States respectfully submits that the Motion should be denied. The Court lacks subject matter jurisdiction over Mattila's request, because (a) the Motion identifies no applicable waiver of sovereign immunity, and none exists until CMS's administrative process has been completed, and because (b) another district court has already ruled that federal law

⁵ CMS additionally reserves the right to pursue recovery of conditional payments from any settlement or judgment in Plaintiff's state court lawsuit. *See* Mot. ¶ 1 n.1.

precludes the relief Mattila seeks in this motion. Additionally, the Motion should be denied because it improperly brings a new claim against the government.

1. The Court Lacks Subject Matter Jurisdiction Over Mattila's Request.

The Motion should be denied because Mattila has not shown that the Court has subject matter jurisdiction over it. *See Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) ("It is to be presumed that a cause lies outside [of the federal courts'] limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction.") (internal citations omitted). Nor can she. The Court lacks subject matter jurisdiction over the Motion for two distinct reasons: (a) the Motion identifies no applicable waiver of sovereign immunity, and (b) the Court is collaterally estopped from exercising subject matter jurisdiction by a sister federal district court's prior ruling on Mattila's request.

a. Sovereign Immunity Bars Mattila's Claim Against the United States.

"It is 'elementary' that the United States, as sovereign, is immune from suit unless it has consented to be sued." *Skwira v. United States*, 344 F.3d 64, 72 (1st Cir. 2003) (quoting *United States v. Mitchell*, 445 U.S. 535, 538 (1980)); *see also F.D.I.C. v. Meyer*, 510 U.S. 471, 475 (1994) ("Absent a waiver, sovereign immunity shields the Federal Government and its agencies from suit."); *United States v. Idaho ex rel. Dir., Idaho Dep't of Water Res.*, 508 U.S. 1, 6 (1993) ("There is no doubt that waivers of federal sovereign immunity must be unequivocally expressed in the statutory text.") (internal quotations omitted). The Motion does not identify any waiver of sovereign immunity that would allow the Court to resolve HHS's right to reimbursement from Mattila's NECC settlement funds. *See Mahon v. United States*, 742 F.3d 11, 14 (1st Cir. 2014) (Plaintiff "has the burden of proving sovereign immunity has been waived."). Nor could it. As explained below, the Medicare statute makes clear that a plaintiff cannot challenge an MSP determination in district court except as permitted by that statute, after the plaintiff completes

CMS's administrative process, which Mattila has failed to do. *See* 42 U.S.C. § 1395ff(b)(1)(A) (incorporating *id.* § 405(g); *id.* § 1395ii (incorporating *id.* § 405(h)); *see also Kaiser v. Blue Cross of Cal.*, 347 F.3d 1107, 1117 (9th Cir. 2003) ("[A]ny waiver of sovereign immunity for cases arising under Medicare . . . is defeated by the exhaustion requirement of 42 U.S.C. § 405(g)."). Without any waiver of sovereign immunity, the Court lacks subject matter jurisdiction over the Motion. *See Meyer*, 510 U.S. at 475 ("[T]he terms of [the United States'] consent to be sued in any court define that court's jurisdiction to entertain the suit.") (internal quotations omitted).

b. Plaintiff's Request Has Previously Been Dismissed for Lack of Subject Matter Jurisdiction and is Therefore Barred by Collateral Estoppel.

Collateral estoppel also precludes the Court from exercising subject matter jurisdiction over the Motion. Collateral estoppel, or issue preclusion, "bars relitigation of any factual or legal issue that was actually decided in previous litigation between the parties, whether on the same or a different claim." *Keystone Shipping Co. v. New Eng. Power Co.*, 109 F.3d 46, 51 (1st Cir. 1997) (emphasis omitted) (quoting *Grella v. Salem Five Cent Sav. Bank*, 42 F.3d 26, 30 (1st Cir. 1994) (internal quotations omitted)). Where, as here, a party seeks relief against the same counter-party in successive actions, collateral estoppel applies if: "(1) the issue sought to be precluded in the later action is the same as that involved in the earlier action; (2) the issue was actually litigated; (3) the issue was determined by a valid and binding final judgment; and (4) the determination of the issue was essential to the judgment." *Ramallo Bros. Printing, Inc. v. El Dia, Inc.*, 490 F.3d 86, 90 (1st Cir. 2007). A dismissal for lack of subject matter jurisdiction is a final judgment for purposes of collateral estoppel. *See, e.g., Muñiz Cortes v. Intermedics, Inc.*, 229 F.3d 12, 14 (1st Cir. 2000) ("Dismissal for lack of subject matter jurisdiction precludes relitigation of the issues determined in ruling on the jurisdictional question.").

As Mattila implicitly acknowledges, *see* Mot. ¶ 16 n.6, the Motion is an attempt to sidestep an order issued by a sister district court two years ago in a lawsuit Mattila filed against CMS. *See Mattila v. CMS*, No. 19-cv-10446, 2020 WL 532400 (E.D. Mich. Feb. 3, 2020). In that case, the district court held that it lacked subject matter jurisdiction to consider Mattila's claims. *See id.* at *6–8. Mattila sought the same relief in that case as she seeks here—i.e., that the court "declare" that CMS's MSP rights "be resolved" for the amount that CMS "would have received under the lien reduction formula" in the MSP Agreement or for "amounts founded and based upon principles of equity and fairness." First Am. Compl. ¶¶ 130–31, *Mattila v. CMS*, No. 2:19-cv-10446 (E.D. Mich. Aug. 27, 2019), ECF No. 13 (attached as Exhibit B). After full briefing on the jurisdictional issue, 6 the Eastern District of Michigan dismissed Mattila's lawsuit on the grounds that her claim "arises under" the Medicare Act and 42 U.S.C. § 405(g)–(h), as incorporated into the Medicare statute, therefore precludes district courts from having subject matter jurisdiction over her claim until she completes CMS's administrative review process. *See Mattila*, 2020 WL 532400, at *4–8.

As detailed in the district court's order, federal law sets forth a five-step administrative process for MSP claims before such claims may be reviewed by a federal district court. *See id.* at *3 (citing 42 U.S.C. § 405(b)). Briefly, those five steps are: (1) an overpayment demand letter, (2) redetermination by the contractor that issued the demand letter, (3) reconsideration by

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⁶ See Def. CMS's Mot. to Dismiss, *Mattila v. CMS*, No. 2:19-cv-10446 (E.D. Mich. Oct. 29, 2019), ECF No. 20; Pls.' Br. in Opp. to Def. CMS's Mot. to Dismiss, *Mattila v. CMS*, No. 2:19-cv-10446 (E.D. Mich. Dec. 18, 2019), ECF No. 24; Def. CMS's Reply in Supp. of its Mot. to Dismiss, *Mattila v. CMS*, No. 2:19-cv-10446 (E.D. Mich. Jan. 17, 2020), ECF No. 27. The foregoing court documents, without exhibits, are attached hereto as Exhibit C.

⁷ The court additionally held that the Administrative Procedure Act did not apply to Mattila's claim because no final agency action was alleged and Mattila "fail[ed] to identify the legal requirement for any discrete agency action that [CMS] was required to take but has failed to do so." *Mattila*, 2020 WL 532400, at *6.

the appropriate CMS Qualified Independent Contractor, (4) review by the Office of Medicare Hearings and Appeals, and (5) review by the Medicare Appeals Council. *See* 42 U.S.C. §§ 405(b); 1395ff. Claims challenging MSP reimbursement demands may be reviewed by a federal district court only after beneficiaries complete this administrative process. *See Mattila*, 2020 WL 532400, at *3; *see also, e.g., Puerto Rican Ass'n of Physical Med. & Rehab., Inc. v. United States*, 521 F.3d 46, 48 (1st Cir. 2008) ("[T]he Supreme Court has interpreted broadly the [42 U.S.C.] section 405(h) bar, holding that a claim 'arises under' the . . . Medicare Act if 'the standing and the substantive basis' for the claim derive from that statute.") (quoting *Weinberger v. Salfi*, 422 U.S. 749, 760–61 (1975)). The Eastern District of Michigan found that Mattila had not yet initiated the first step of the administrative process by submitting to CMS information needed to issue an overpayment demand letter. *See Mattila*, 2020 WL 532400, at *6. The court held that Mattila's failure to exhaust the required administrative remedies precluded the district court from having jurisdiction over the claim. *See id.* at *7.

The result must be the same here. Conspicuously absent from Mattila's Motion is any allegation that she has in the past two years completed, or even initiated, the administrative process. See Mot. ¶ 16. The Motion is therefore collaterally estopped from relitigating whether Mattila's claim "arises under" the Medicare statute and whether 42 U.S.C. § 405(g)–(h) precludes judicial review until all administrative remedies have been exhausted. See Cooper v. Principi, 71 Fed. Appx. 73, 75 (1st Cir. 2003) (affirming dismissal of claims against a federal agency as collaterally estopped by a prior holding that a federal statute, in effect, barred subject matter jurisdiction); Tucker v. Sec'y of Health & Human Servs., 588 Fed. Appx. 110, 114 (3d

⁸ Plaintiff suggests only that she has engaged in pre-process negotiations with CMS to resolve its Medicare lien against Plaintiff's NECC settlement funds. *See* Mot. ¶ 16 n.6.

Cir. 2014) (doctor's second complaint against HHS was collaterally estopped by prior complaint's dismissal for lack of subject matter jurisdiction due to doctor's failure to exhaust administrative review).

Rather than confronting the plain federal law requiring exhaustion, the Motion attempts to sidestep the Michigan court's ruling by asserting, without citing legal authority, that this Court has jurisdiction "by virtue of" (1) the Court's "having presided over the NECC cases, . . . in which Medicare was a settling party / participant by contractually agreeing to . . . the [MSP Agreement]," Mot. ¶ 16 n.6, and (2) the Tort Trust Agreement's partial withdrawal to the Court of "issues pertaining to the liquidation or estimation of contingent or unliquidated personal injury tort or wrongful death claims against the [NECC] Estate for purposes of distribution," Mot. ¶ 19. Neither assertion meets Mattila's jurisdictional burden.

The Motion's first argument—that jurisdiction exists because the Court "presided over the NECC cases" and approved the Trustee's entry into the MSP Agreement—is incorrect.

Merely because HHS was a signatory to the MSP Agreement does not give the Court subject matter jurisdiction to determine the amount that HHS should be reimbursed for its conditional payments, and the Motion identifies no authority suggesting otherwise. The Court's approval of the MSP Agreement does not, and could not, purport to imbue the Court with subject matter jurisdiction to modify the agreement's terms by allowing a Medicare beneficiary who opted out to opt back in or to adjudicate the amount that HHS is entitled to be reimbursed for its conditional payments. *See Kokkonen*, 511 U.S. at 377 ("Federal courts are courts of limited jurisdiction" having "only that power authorized by Constitution and statute, which is not to be expanded by judicial decree.") (citations omitted). Plaintiff must instead demonstrate both a statutory grant of subject matter jurisdiction and an affirmative congressional waiver of

sovereign immunity. Neither exist here. Instead, as the Eastern District of Michigan recognized, federal law specifically *deprives* district courts of subject matter jurisdiction over NECC-related MSP reimbursement rights until the administrative process has been completed. *See Mattila*, 2020 WL 532400, at *4–8.

Further, the Supreme Court has made clear that even when a court had statutory subject matter jurisdiction over the original underlying claim—which was not the case here—approving an agreement settling that claim would not give a court continued jurisdiction over the agreement itself, *see Kokkonen*, 511 U.S. at 381, much less give the court jurisdiction over claims that it never had jurisdiction to address and that federal statute requires be adjudicated through an administrative process, as is the case here. For all of these reasons, the Court's approval of the MSP Agreement did not give it subject matter jurisdiction over this Motion.

The Motion's invocation of the Tort Trust Agreement's jurisdictional provision is similarly unavailing. District courts do not derive jurisdiction over the government from judicially-approved agreements that are not founded on a waiver of sovereign immunity specifically granted by statute. Further, the Motion does not lie within the jurisdictional provision it cites, because the Motion does not concern "liquidation or estimation" of—i.e., assigning a dollar amount to—Mattila's claim against NECC. Mot. ¶ 19.

For all of these reasons, the result here must be the same as when Mattila's request was before the Eastern District of Michigan. Congress required the government's MSP recovery to

⁹ Federal law also specifies the particular district court in which an action seeking review of a Medicare decision must be brought, which may preclude Mattila from bringing her request in this Court even if she were to complete the administrative process. *See* 42 U.S.C. § 405(g) (an action seeking judicial review "shall be brought in the district court of the United States for the judicial district in which the plaintiff resides, or has his principal place of business, or, if he does not reside or have his principal place of business within any such judicial district, in the United States District Court for the District of Columbia").

be adjudicated through CMS's administrative process. Until that process is completed, federal district courts lack subject matter jurisdiction to adjudicate the relief Mattila seeks.

2. The Motion is Procedurally Defective Because it Asserts a New Claim.

Further, the Motion should be denied because it is procedurally improper. The Motion seemingly asserts a claim for "equitable and/or declaratory relief" curtailing the government's MSP rights. Mot. ¶ 17. But asserting a new claim by motion is procedurally improper, particularly where, as here, the purported defendant is not even a party to the litigation. See Fed. R. Civ. P. 3–5, 8, 10, 12–15; see also Hernandez v. Lord, No. 3:19-cv-00151, 2020 WL 6532818, at *2 (D. Alaska Nov. 5, 2020) (Rule 15(a) "[p]lainly . . . means that a plaintiff cannot simply add on new claims or defendants by motion or declaration."). Mattila has not alleged any effort to join HHS or HHS Secretary Becerra as a party to either this multidistrict litigation ("MDL"), which was closed in 2018, or to Mattila's underlying lawsuit, which was closed in 2016, see Mattila v. New Eng. Compounding Pharmacy, Inc., No. 1:13-cv-10430 (D. Mass.). To bring a claim against an agency or officer of the United States, like HHS or Secretary Becerra, a party must file a pleading and serve both the United States and the agency or officer in the manner required by Federal Rule of Civil Procedure 4(i). Mattila has filed no such pleading and alleged no such service here.

Mattila appears to assert that HHS's having entered into the MSP Agreement made HHS a party to this MDL. *See* Mot. ¶ 16 n.6. The Federal Rules of Civil Procedure do not support that view, and the Motion cites no authority for that proposition. ¹0 Indeed, this case's own

¹⁰ The United States' limited, non-substantive intervention in this matter in 2015 to protect the United States' interests in an ongoing criminal investigation does not grant the Court jurisdiction to adjudicate the Motion. *See* Mot. of the United States for Leave to Intervene and for a Stay of Certain Deps. Pending Resol. of Related Crim. Proc., ECF No. 2209. Such limited interventions do not make an intervenor a party to a lawsuit. *See Beckman Indus. Inc. v. Int'l Ins. Co.*, 966

history belies that assertion. For instance, in July 2016, rather than simply ordering HHS to appear at an upcoming hearing on the status of the MSP Agreement negotiations, as it would a party, the Court acknowledged HHS's lack of party status and directed lead counsel for plaintiffs to notify HHS that its attendance at the hearing was required. *See* Status Conf. Tr. 9:12–22 (July 28, 2016), ECF No. 3045; *see also* Lead Counsel's Notice to CMS, U.S. Dep't of Just., and All Interested Parties, ECF No. 3026.

Because a new claim cannot be brought by motion, the Motion should be denied.

CONCLUSION

For the reasons stated above, the Motion should be denied.

Dated: May 11, 2022 Respectfully submitted,

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F.2d 470, 474 (9th Cir. 1992) (non-parties seeking to intervene for a limited purpose "are not becoming parties to the litigation").

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document filed through the ECF system will be sent electronically to counsel of record who are registered participants as identified on the Notice of Electronic Filing (NEF).

Dated: May 11, 2022 By: /s/ Bethany Theriot

BETHANY THERIOT